

DEC 20 2002

**510(K) SUMMARY OF SAFETY AND EFFECTIVENESS**

This summary of safety and effectiveness is being submitted in accordance with the requirements of The Safety Medical Device Act of 1990 and 21 CFR Part 807.92

**510(k) Number:**

K 023408

**Date of Summary Preparation:**

October 5, 2002

**Submitter:** Applied Biotech, Inc.  
**Contact Person:** Vivianne Noetzel  
**Phone:** 858-756-8483  
**FAX:** 858-759-7492  
**Address:** P.O. Box 9433  
17394 Via Del Bravo  
Rancho Santa Fe, California 92067  
**Manufacturing Site:** Applied Biotech, Inc.  
10237 Flanders Court  
San Diego, California 92121  
**Phone:** 858-587-6771  
**Establishment Number:** 2028231

**Device Trade Name:** InstaCheck® Menopause Predictor Test  
**Device Common Name:** Follicle Stimulating Hormone Test  
**Device Classification:** Class 1 (21 CFR 862.1300)  
**Device Product Code:** CGJ  
**Performance Standards:** None established (as a medical device) under Section 514.  
**Device Description:** One step immunoassay for the detection of FSH in urine.

**Intended Use** The InstaCheck® Menopause Predictor Test is an *in vitro* diagnostic screen for the detection of FSH in urine. Changes in FSH levels in human urine are related to the symptoms associated with stages of menopause. The InstaCheck® Menopause Predictor Test is used to obtain a visual, qualitative result and is intended for over-the-counter sale to laypersons.

**Indication for Use** The InstaCheck® Menopause Predictor Test is an *in vitro* diagnostic screen for the detection of FSH in urine. Changes in FSH levels in human urine are related to the symptoms associated with stages of menopause. The InstaCheck® Menopause Predictor Test is used to obtain a visual, qualitative result and is intended for over-the-counter sale to laypersons.

**Substantial Equivalence Claim to:**

SURESTEP FSH Menopause Test	K010556
Genua Menopause Monitor Test Kit	K002450

**Summary of Device Consumer Testing:**

**STUDY CONCLUSION**

The consumer study demonstrated that when the InstaCheck<sup>®</sup> Menopause Predictor Test was performed by a general public consumer population of diverse age, sex and educational background, there was an overwhelming favorable assessment of the package insert, with respect to readability (98.5%) and comprehension (99.6%).

The consumer study demonstrated that the consumer could complete the test 100% of the time. The consumer study also demonstrated that the consumer could perform the test with excellent accuracy (>99%).



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

DEC 20 2002

Applied BioTech, Inc.  
c/o Ms. Vivianne Noetzel  
Noetzel Terratech  
P.O. Box 9433  
Rancho Santa Fe, CA 92067

Re: k023408  
Trade/Device Name: InstaCheck<sup>®</sup> Menopause Predictor Test  
Regulation Number: 21 CFR 862.1300  
Regulation Name: Follicle-stimulating hormone test system  
Regulatory Class: Class I  
Product Code: CGJ  
Dated: October 5, 2002  
Received: October 10, 2002

Dear Ms.Noetzel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

Page 2 –

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive, slightly slanted style.

Steven I. Gutman, M.D., M.B.A.  
Director  
Office of *In Vitro* Diagnostic Device  
Evaluation and Safety  
Center for Devices and  
Radiological Health

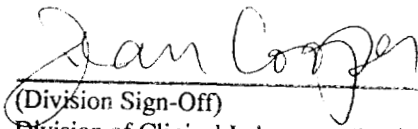
Enclosure

INDICATIONS FOR USE STATEMENT

**510(k) Number:** K023408

**Device Name:** InstaCheck® Menopause Predictor Test

**Intended Use** The InstaCheck® Menopause Predictor Test is an *in vitro* diagnostic screen for the detection of human Follicle Stimulating Hormone, FSH, in urine. Changes in FSH levels in human urine are related to the symptoms associated with stages of menopause. The InstaCheck® Menopause Predictor Test is used to obtain a visual, qualitative result and is intended for over-the-counter sale to laypersons.

  
(Division Sign-Off)  
Division of Clinical Laboratory Devices  
510(k) Number K023408

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDHR, office of Device Evaluation (ODE)

Prescription Use \_\_\_\_\_

OR

Over-The-Counter Use ✓